Original Article

Comparison of Performance of Digital Hemoglobinometer over Automated Hematology Analyzer for Hemoglobin Estimation and Its user-friendliness among the Pregnant Women in Selected District Hospitals of Madhya Pradesh

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Abstract

Context: There is a need for a simple screening method for the detection of anemia that can be used by public health workers in the field. **Aims:** The aim of this study was to compare two methods for hemoglobin estimation, i.e., automated hematology analyzer and Digital Hemoglobinometer, and to find out the sensitivity and specificity of Digital Hemoglobinometer for the estimation of hemoglobin. **Subjects and Methods:** A hospital-based cross-sectional study was carried out for 6 months from April to September 2017 in a District Hospital of five High Priority Districts of Madhya Pradesh. Two hundred and sixty antenatal females per district were selected for the study. **Results:** The mean hemoglobin by autoanalyzer is 10.19, and that by Digital Hemoglobinometer device is 9.89. Overall, sensitivity of Digital Hemoglobinometer for hemoglobin estimation was calculated to be 89.4% and specificity was calculated to be 63.6%. Positive predictive value was found to be 82.6% and negative predictive value was 75.8% compared against AutoAnalyser (gold standard). **Conclusions:** As the Digital Hemoglobinometer device has high sensitivity and specificity and good diagnostic accuracy, it must be used at the community level in resource-poor setting for hemoglobin estimation. In primary health-care conditions, Digital Hemoglobinometer can significantly reduce misdiagnosis of anemia compared with clinical assessment alone.

Keywords: Anemia, antenatal clinic female, Auto Analyser, Digital Hemoglobinometer, Madhya Pradesh

Introduction

Assessment of hemoglobin is one of the most reliable indicators for anemia and is widely used to screen for anemic individuals and to evaluate responses to interventions.[1] Commonly used methods to estimate hemoglobin in a community setting are clinical examination for pallor, Sahli's method, World Health Organization color scale, and HemoCue. Unfortunately, these methods have several limitations, ranging from the lack of accuracy to complexity to high cost.[2,3] There are various methods of hemoglobin estimation, invasive and noninvasive, of which the invasive type varies from simple paper scale reading to measurement by photometer, i.e., HemoCue and Sahli's method. The noninvasive types are the pulse oximetry, photoplethysmography, optoacoustic method, diffuse reflectance spectroscopy, and imaging-based technique, each with its own advantages and limitations. Accurate quantitative point of care diagnostic tests can confirm the diagnosis of anemia through measurement of a decreased amount of red blood cells or decreased hemoglobin concentration in the blood, but these are not suitable in most primary health-care settings with very low resources because they either require constant quality control by trained staff, use toxic or expensive reagents and consumables, or depend on electricity supply.[4]

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Diagnosis is thus often based on clinical signs alone such as conjunctival, palmar, and nail bed pallor. None of these signs, whether combined or singly, yield an acceptable diagnostic accuracy.[5] This leaves many cases undetected and untreated and also possesses the risk of unnecessary and potentially harmful blood transfusions, increasing the risk of transmission of blood-borne pathogens, and wasting resources in case of misdiagnosed severe anemia.[6]

There is a need for a simple screening method for the detection of anemia that can be used by public health workers in the field. Any method of screening or monitoring individuals for anemia at primary care level should be cheap, simple to operate, sturdy enough for field use, dependent neither on electricity nor batteries, and reasonably accurate. It should also use a minimum of materials that require regular replacement and should give immediate results. Hemoglobin concentration is routinely measured using Automated Hematology Analyzers (AHAs). Although these are very accurate and reliable, they are expensive, and problems of samples' transport to the laboratory may delay treatment.[7] In clinical measurement, comparison of a new measurement technique with an established one is often needed to see whether they agree sufficiently for the new to replace the old. Therefore, this study was aimed to compare two hemoglobin testing methods and to assess the utility of Digital Hemoglobinometer against a standard hematology AutoAnalyzer and to ascertain whether Digital Hemoglobinometer method could replace the traditional hematology AutoAnalyzer for hemoglobin screening. The objectives of the study were (1) to compare two methods for hemoglobin estimation, i.e., AHA and Digital Hemoglobinometer and (2) to find out the sensitivity and specificity of Digital Hemoglobinometer for the estimation of hemoglobin.

Subjects and Methods

It was a hospital-based cross-sectional study carried out for 6 months from April to September 2017 in a District Hospital of five High Priority Districts of Madhya Pradesh were selected based on case load and availability of AutoAnalyzer. The study participants were antenatal mothers attending the antenatal clinics of selected district hospital. The sample size was estimated according to the prevalence of anemia, that is, 54.6% (NFHS IV MP). Assuming a sensitivity of 80% and specificity of 80% and precision of 0.03, a sample size of 1265 was considered adequate for the study. Thus, it was estimated to be 253 antenatal females per district which rounded off to 260 tests (antenatal mothers) was covered to assess the diagnostic accuracy of each method. Thus, a total of 1300 antenatal females were included in the study. Inclusion criteria were (1) pregnant women attending the antenatal clinic for the first time in the study period and (2) pregnant women giving consent for the study. Pregnant women attending the hospital with severe illness were excluded from the study. Sample collection – blood samples were collected from consented participants within the study group reporting to the hospital after study procedures had been explained to them. Following aseptic precautions, the venous blood was drawn in the ethylenediaminetetraacetic acid (EDTA) vial using disposable syringes. Venous blood collected from the participants was processed to estimate their Hb content using two different methods. Two investigators were positioned in each district at the site of sample collection to ensure blinding. Time-to-time calibration of the machine was ensured. Ethical approval was obtained from the Institutional Ethical Committee for the study. Statistical analysis – The data were entered into the Microsoft Excel 2007, and the analysis was done using Epi Info™ version 7.2.2.6 software (CDC). Epi Info™ is a trademark of the Centers for Disease Control and Prevention (CDC). The software is in the public domain and freely available for use, copying translation and distribution.[8]

AutoAnalyzer – The AutoAnalyzer is an automated blood cell counter intended for *in vitro* diagnostic use in clinical laboratories. It measures the hemoglobin concentration using a noncyanide hemoglobin method. The instrument has been proven to provide accurate and reliable results including hemoglobin concentrations. The test is performed by collecting 2 ml of blood in an EDTA vial using disposable syringe under all aseptic precautions. The test is performed as stated in the manufacturer's manual using the reagents/kits provided with the instrument as recommended by manufacturers. The AutoAnalyzer used in the study was manufactured by Celltac by Nihon Kohden MEK 6420P (Sagar), Mindray BC 2800 (Raisin), Mindray BC 5000 (Shahdol), Mindray BC 5300 (Anuppur), and URIT 2900 (Damoh).[9]

Digital Hemoglobinometer – It is a device in response to the need for a "simple, cheap, and robust device to measure hemoglobin by health workers outside the laboratory." Digital Hemoglobinometer (HCG TRIESTA laboratory) is palm-sized nanobioelectronic device with self-calibration sensors that takes <60 s for each hemoglobin estimation. The Digital Hemoglobinometer System is based on the principle of reflectance photometry. Capillary, venous, or arterial whole-blood sample can be used for the hemoglobin estimation with the requirement of only 8 ml of blood sample. It has a rechargeable battery of 3.6 V that makes its suitable for usage in places with poor electricity supply. This device can be used in temperature range of 5–45°C. The device can store up to 1000 results for date and time, and easy record maintenance is possible using mobile application. The range of measurement is 0–25 mg/dl.[10] The Digital Hemoglobinometer Strips are thin plastic strips which contain chemical reagents. The strips vial has a unique code which needs to be entered in the device each time the strip is loaded. The pack also contains 50 sterile lancets.

Results

The women attending the antenatal clinic were mostly of the age group of 24–26 years (32.7%) followed by 21–23 years (31.5%), <20 years (17.1%), and 27–29 years (10.8%). Only 7.9% of women belonged to the age group of 30 years and above.

The mean hemoglobin by AutoAnalyzer is 10.19, and that by Digital Hemoglobinometer device is 9.89. Median by AutoAnalyzer is 12.4 and by Digital Hemoglobinometer device is 13.65. There is only slight difference in the minimum values found by them. Z-score of two means of both the methods, i.e., AutoAnalyzer and Digital Hemoglobinometer, was calculated, and the result came out to be statistically nonsignificant. Hence, we can say that the observed difference between the two methods is just by chance.

Table 1 shows the number of women diagnosed under each category by the two methods. The tables show that 34.07% of the women were classified as no anemia by AutoAnalyzer, whereas 28.61% were not anemic by Digital Hemoglobinometer. Furthermore, 25.61%, 37.15, and 3.15% were classified as mild, moderate, and severe anemia, respectively, with AutoAnalyzer, whereas 22.53%, 43.53%, and 5.30% women were classified as mild, moderate, and severe anemia, respectively, by Digital Hemoglobinometer. The reference test, i.e., AHA detected more number of no anemia and mild anemia, whereas the index test, i.e., Digital Hemoglobinometer, detected more cases of moderate and severe anemia.

Sensitivity, specificity, and positive and negative predictive values (NPVs) of Digital Hemoglobinometer were calculated over AutoAnalyzer (gold standard). Table 2 shows that overall sensitivity of Digital Hemoglobinometer was calculated to be 89.4% and specificity was calculated to be 63.6%. Positive predictive value was found to be 82.6% and NPV was 75.8% compared against AutoAnalyzer (gold standard). For detection of mild anemia, sensitivity was calculated to be 60.7% and specificity was 72.4%. This means that the Digital Hemoglobinometer device is 60.7% sensitive to detect mild anemia. Similarly, Digital Hemoglobinometer is 97.9% sensitive to detect moderate anemia. Furthermore, the sensitivity of Digital Hemoglobinometer is 100%, and specificity is 98% for the detection of severe anemia, thereby indicating that Digital Hemoglobinometer is a very effective device in identifying anemia.

Discussion

Accurate determination of hemoglobin concentration is a common element in assessing the extent of anemia and making a decision regarding treatment. This decision should be made based on the reliable and rapidly assessed laboratory tests. The Digital Hemoglobinometer is a portable device for measuring hemoglobin concentration, and it requires very little staff training thus making it a very useful tool in resource-limited areas such as field conditions since it can easily be transported. In this study, we compared it with AutoAnalyzer used in the laboratory. We found no significant differences in the hemoglobin concentrations determined by the two methods. Our study is in agreement with other studies conducted in other settings to support the use of the device. These include the studies conducted by von Schenck *et al*. which suggested that HemoCue equipment is easy to handle.[11] Van de Louw *et al*., among patients with gastrointestinal bleeding, found that the mean difference between HemoCue and hemoglobin (bias) was −0.06 g/dl and standard deviation (precision) was 0.87 g/dl (95% Confidence interval – 1.8 − 1.68).[12] Rippmann *et al*., among surgical patients, in their study concluded that HemoCue underestimates the Hb concentration as determined by a CO-Oximeter by 2-5% and exhibits a significantly higher variability.[13] Neville RG *et al*., within urban general practice, found that the mean hemoglobin concentration by HemoCue was found to be 137 ± 23 g/l (range 64–192). The corresponding laboratory figures were mean 135 ± 1 and range 78–180.[14] Rechner *et al*., among neonates;[15] Lardi *et al*., among patients undergoing aortic surgery in the theater;[16] Sari *et al*., among Indonesian mothers;[17] and Radtke *et al*., among blood donors,[18] also showed the utility of Digital Hemoglobinometer comparable to gold standard. Whereas, studies conducted by Zhou *et al*. among pregnant women in a higher altitude area of Tibet, China,[19] and Bhaskaram *et al*., among apparently healthy children of 1–6 years[20] do not support the use of the HemoCue in their various study populations. Since Digital Hemoglobinometer is portable, simple to use, and gives results immediately, it is recommended as an excellent screening method for the detection of anemia in cellular Hb concentration, primary health care (PHC), blood bank, and field setup. However, Digital Hemoglobinometer costs a considerable amount of money, and this should be considered while planning and budgeting for data collection.

Conclusions

As the Digital Hemoglobinometer device has high sensitivity and specificity and good diagnostic accuracy, it must be used at the community level in resource-poor setting. In PHC conditions, Digital Hemoglobinometer can significantly reduce misdiagnosis of anemia compared with clinical assessment alone.

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Table 1: Distribution according to the severity of anemia as per the World Health Organization Classification

WHO criteria	No anemia	Mild anemia	Moderate anemia	Severe anemia	Total
For pregnant women (g/dl)	>11	10-10.9	7-9.9	<7	
Number of women within this range by AutoAnalyzer hemoglobin (%)	443 (34.07)	333 (25.61)	483 (37.15)	41 (3.15)	1300 (100)
Number of women within this range by Digital Hemoglobinometer (%)	372 (28.61)	293 (22.53)	566 (43.53)	69 (5.30)	1300 (100)

WHO: World Health Organization

Table 2: Sensitivity and specificity of Digital Hemoglobinometer as compared to an AutoAnalyzer

Method Digital hemoglobinometer	AutoAnalyzer		
	Anemia present (≤10.9 g/dl)	Anemia absent (≥11 g/dl)	Total
Anemia present (≤10.9 g/dl)	767 (TP)	161 (FP)	928
Anemia absent (≥11 g/dl)	90 (FN)	282 (TN)	372
Total	857	443	1300

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Conflicts of interest

There are no conflicts of interest.

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